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EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	**PAPER NUMBER**
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/719,532	FOLLANSBEE, DAVID	
	Examiner	Art Unit	
	Nora M. Rooney	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 7-24* is/are pending in the application.

4a) Of the above claim(s) *7,9,10 and 13-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 8 AND 11-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-2 and 7-24 are pending.

2. Claims 7, 9-10 and 13-24 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Claims 1-2, 8 and 11-12 are currently under examination as they read on a pharmaceutical composition comprising at least one helminth-based agent and a vaccine comprising the pharmaceutical composition.

Claim Objections

4. Claim 1 is objected to because of the following informalities: The group consisting of one or more of the following is improper Markush language because the species is selected from the group and there are two species listed. A species is not two species. Appropriate correction is required.

5. In view of the amendment filed on 07/23/2007, only the following rejections are maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2, 8 and 11-12 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and/or use the invention.

The specification does not provide reasonable enablement for: **A pharmaceutical formulation for treating allergies or asthma in a mammal** comprising **at least one helminth-based antigen**, wherein said **helminth-based antigen** comprises **a protein obtained or derived from** a species selected from the group consisting of one or more of the following: Capillaria hepatica and Dicrocoelium dendriticum, wherein **said helminth-based antigen** increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal **to a plurality of antigens** of claim 1; further comprising at least one pharmaceutically acceptable compound selected from the group consisting of one or more of the following: adjuvants, carriers and diluents of claim 2; wherein **said protein is recombinant** of claim 8; wherein said pharmaceutical formulation comprises in a form selected from the group consisting of one or more of the following: injectable fluids, suppositories, powder, tablets, capsules, syrups, suspensions, liquids and elixirs of claim 11; or an extract **for treating allergies or asthma in a mammal** comprising the

pharmaceutical formulation of claim 1 in an amount sufficient to regulate IgE of claim12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons as set forth in the Office Action mailed on 03/19/2007.

Applicant's arguments filed on 07/23/2007 have been fully considered, but are not found persuasive.

Applicant argues that the amendments filed on 07/23/2007 overcome the rejections under 112, first paragraph. Applicant also argues that the Examiner's request for data was based on the breadth of the previously presented claims. In view of the amendments, Applicant asserts that the specification provides ample support for the claims. Applicant also argues that any subsequent argument by the Examiner that data is required to support the amended claims would be unfounded because it is well-established that an applicant is not required to submit data to establish enablement, as in *Ex Parte Kyle.* Using the reasoning of Ex Parte Kyle, Applicant asserts that utility of the instant claims should not be questioned because the Examiner has not rejected any of the claims under § 101 for lack of utility. Because the Examiner relies upon prior art that anticipates or obviates the claimed invention, it would be inconsistent for the Examiner to later allege that the asserted utility of a helminthic antigen for treating allergies or asthma is not believable to persons skilled in the art.

It is the Examiner's position that although there is no requirement for data to establish enablement, the Examiner has provided data to show that the art is highly unpredictable and that it would require undue amount of experimentation to practice the invention as claimed to treat

allergies or asthma in a mammal. Applicant has not provided disclosure or data in the specification that overcomes the showing of unpredictability in the prior art. As stated in the Office Action mailed on 03/19/2007, although the benefit of some helminths to downregulate allergic responses has been documented, Carvalho et al. (PTO-892 mailed 03/19/2007, Page 2, Reference V) teaches that helminths synthesize protease molecules that provoke allergenic responses and that excretory/secretory products of helminths can actually induce Th2 responses. In addition, some helminthic antigens cross-react with allergens which can increase allergic reaction in atopic individuals and initiate allergic diseases in non-atopic individuals (In particular, page 529, paragraph spanning left and right columns). Wilson et al. (PTO-892 mailed on 03/19/2007, Page 3, Reference U) teaches that helminth-driven suppression of allergic inflammation is mediated by CD25+ upregulated T cells. However, expression of CD25 depends on both many defined and as-yet unknown factors (In particular, abstract, page 1203, 'Anti-CD25 antibodies block supression' section). Expression is associated with the induction of specific cytokines, namely IL-10 and TGF- β, but there is no evidence in the reference or otherwise that all helminth antigens upregulate CD25 on T cells. Cooper et al. (PTO-892 mailed 03/19/2007, Page 2, Reference W) teaches that geohelminthic parasites secrete potent allergens and can be capable of enhancing allergic inflammation as evidenced by asthmatic symptom decrease upon anti-helminthic treatments (In particular, page 399 second to last paragraph of left column). Further, Falcone et al. provides insight into the state of the art in disclosing that, as of 2005, clinical trials were ongoing (PTO-892 mailed 03/19/2007, Page 2, Reference X). If positive immunosuppressive results are demonstrated, those parasites will be then mined for immuno-suppressive molecules that can be used in appropriate sustained-delivery formulations

to mimic successful immunological responses induced by natural infections. (In particular, page 159, paragraph spanning left and right columns). Therefore, the art is highly unpredictable and it would require and undue amount of experimentation to practice the claimed invention.

Further, the specification fails to provide guidance as to how to treat all allergy. Allergy is a very complex disease involving a large number of diverse antigens. The treatment of any and all allergic diseases and symptoms using any and all helminthic antigens has not been adequately been disclosed in the specification. The specification also does not sufficiently enable the prevention of any specific allergy with any specific helminthic antigen.

It is also the Examiner's position that the Applicant has only disclosed the theoretical use of "antigenic material" and "antigenic protein" to invoke "the desired immune response" in Examples 1 and 2 (In particular, page 32). The specification is directed to the use of any helminthic agent/ antigen given to any animal to reduce any allergy. On page 7, the helminthic antigen is preferably isolated from Capillaria hepatica and/or Dicrocoelium dendtritium and/or Schistosomes.

Further, any helminthic extract obtained or derived from Capillaria hepatica and/or Dicrocoelium dendtritium as encompassed by claim 12, such as a crude extract, will contain helminthic components that are not responsible for decreasing allergy and may actually cause a separate inflammatory response or other undesirable side-effects.

The specification also does not provide any support for a helminth-based antigen that is "derived" from Capillaria hepatica or Dicrocoelium dendtritium. The term "derived" encompasses any antigen having any number of undisclosed mutations, deletions or additions. The specification has not disclosed the use of any antigen comprising a protein "derived" from Capillaria hepatica or Dicrocoelium dendtritium.

8. Claims 1-2, 8 and 11-12 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of: **A pharmaceutical formulation for treating allergies or asthma in a mammal** comprising **at least one helminth-based antigen**, wherein said **helminth-based antigen** comprises **a protein obtained or derived from** a species selected from the group consisting of one or more of the following: Capillaria hepatica and Dicrocoelium dendriticum, wherein **said helminth-based antigen** increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal **to a plurality of antigens** of claim 1; further comprising at least one pharmaceutically acceptable compound selected from the group consisting of one or more of the following: adjuvants, carriers and diluents of claim 2; wherein **said protein is recombinant** of claim 8; wherein said pharmaceutical formulation comprises in a form selected

from the group consisting of one or more of the following: injectable fluids, suppositories, powder, tablets, capsules, syrups, suspensions, liquids and elixirs of claim 11; or an extract **for treating allergies or asthma in a mammal** comprising the **pharmaceutical formulation** of claim 1 in an amount sufficient to regulate IgE of claim12 for the same reasons as set forth in the Office Action mailed on 03/19/2007.

Applicant argues that the amendments filed on 07/23/2007 overcome the rejections under 112, first paragraph. Applicant also argues that the Examiner's request for data was based on the breadth of the previously presented claims. In view of the amendments, Applicant asserts that the specification provides ample support for the claims. Applicant also argues that any subsequent argument by the Examiner that data is required to support the amended claims would be unfounded because it is well-established that an applicant is not required to submit data to establish enablement, as in *Ex Parte Kyle*. Using the reasoning of Ex Parte Kyle, Applicant asserts that utility of the instant claims should not be questioned because the Examiner has not rejected any of the claims under § 101 for lack of utility. Because the Examiner relies upon prior art that anticipates or obviates the claimed invention, it would be inconsistent for the Examiner to later allege that the asserted utility of a helminthic antigen for treating allergies or asthma is not believable to persons skilled in the art.

It is the Examiner's position that neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms, that are common to the genus. That is, the specification provides neither a representative number of helminthic antigens to describe the claimed genus, nor does it provide a description of structural

features that are common to species of helminth-based antigen or protein isolated from a helminth. The specification provides no description what helminthic proteins or helminthic antigens would work in the present invention; in essence, the specification simply directs those skilled in the art to go figure out for themselves what helminthic antigen preparations to use. The claims read on any as yet undiscovered helminths and helminthic proteins and antigens. Therefore, the specification's disclosure is inadequate to describe the claimed genus of any helminthic antigen for use in the claimed invention.

Further, the specification fails to provide guidance as to how to treat any allergy. The term "allergy" includes diseases as diverse as food allergies, metal allergies, contact allergy and chronic diseases like asthma, all of which have distinct pathogenesis. The specification does not describe the use of the claimed invention to treat any allergy.

The specification also does not provide any describe the use of any helminth-based antigen that is "derived" from Capillaria hepatica or Dicrocoelium dendtritium. The term "derived" encompasses any antigen having any number of undisclosed mutations, deletions or additions. The specification has not adequately described the use of any antigen comprising a protein "derived" from Capillaria hepatica or Dicrocoelium dendtritium.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2 and 11-12 stand rejected under 35 U.S.C. 102(b) as being anticipated by De Macedo et al. (PTO-892 mailed on 03/19/2007, Reference U) for the same reasons as set forth in the Office Action mailed on 03/19/2007.

Applicant's arguments filed on 07/23/2007 have been fully considered, but are not found persuasive.

Applicant argues that there is no teaching, suggestion or motivation in the cited art to use a helminth-based antigen that increases IgE levels in order to treat allergies.

It is the Examiner's position that the claims are drawn to a composition. The prior art anticipates the claimed invention because the intended use of the composition carries no patentable weight. De Macedo et al. teaches Ascaris suum extract (helminth-based antigen comprising a protein derived from Capillaria hepatica or Dicrocoelium dendtritium, extract) isolated from live Ascaris suspended in borate buffered saline (carrier/diluent) (In particular, page 702, section entitled 'Antigens). The antigen was administered to mice (immunogenic amount) with ovalbumin (Oa); dinitrophenol ovalbumin (DNP-Oa); and/or aluminum hydroxide

(adjuvant) by injection (injectable liquid, vaccine) (In particular, page 702, column spanning left and right columns).

A composition is a composition, regardless of its intended use. Therefore, the reference teachings anticipate the claimed invention.

Claims 1-2 and 11 are included in this rejection because the term "derived" in claim 1 opens the claim up to include any protein that is "derived" from Capillaria hepatica or Dicrocoelium dendtritium, which include any number of substitutions, deletions or additions. Therefore, any protein of Ascaris suum having any degree of homology to any protein of Capillaria hepatica or Dicrocoelium dendtritium anticipates the claimed invention. Further, claims 1-2 and 11-12 are included in this rejection because because the claimed functional limitation (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to geater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens) would be inherent properties of the referenced pharmaceutical formulation. When a claim recites using an old composition or structure (e.g.helminth based antigen pharmaceutical formulation) and the use is directed to a result or property of that composition or structure (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to geater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52

USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The prior art teachings anticipate the claimed invention.

11. Claims 1-2 and 11-12 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ferreira et al. (PTO-892 mailed on 03/19/2007; Reference W) for the same reasons as set forth in the Office Action mailed on 03/19/2007.

Applicant's arguments filed on 07/23/2007 have been fully considered, but are not found persuasive.

Applicant argues that there is no teaching, suggestion or motivation in the cited art to use a helminth-based antigen that increases IgE levels in order to treat allergies.

It is the Examiner's position that the claims are drawn to a composition. The prior art anticipates the claimed invention because the intended use of the composition carries no patentable weight. Ferreira teaches Ascaris suum extract (helminth-based antigen comprising a protein derived from Capillaria hepatica or Dicrocoelium dendtritium, extract) suspended in complete Freund's adjuvant administered to mice (immunogenic amount) with ovalbumin by injection (injectable liquid, vaccine) (In particular, pages 202-203, sections on 'Reagents, Antigens and Cell Line' and 'Immunization and Skin Testing.'

A composition is a composition, regardless of its intended use. Therefore, the reference teachings anticipate the claimed invention.

Claims 1-2 and 11 are included in this rejection because the term "derived" in claim 1 opens the claim up to include any protein that is "derived" from Capillaria hepatica or Dicrocoelium dendtritium, which include any number of substitutions, deletions or additions. Therefore, any protein of Ascaris suum having any degree of homology to any protein of Capillaria hepatica or Dicrocoelium dendtritium anticipates the claimed invention. Further, claims 1-2 and 11-12 are included in this rejection because because the claimed functional limitation (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens) would be inherent properties of the referenced pharmaceutical formulation. When a claim recites using an old composition or structure (e.g. helminth based antigen pharmaceutical formulation) and the use is directed to a result or property of that composition or structure (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The prior art teachings anticipate the claimed invention.

12. Claims 1-2, 8 and 11-12 stand rejected under 102(a) as being anticipated by U.S. Patent 6,207,158 (PTO-892 mailed on 03/19/2007, Reference A) for the same reasons as set forth in the Office Action mailed on 03/19/2007.

Applicant's arguments filed on 07/23/2007 have been fully considered, but are not found persuasive.

Applicant argues that there is no teaching, suggestion or motivation in the cited art to use a helminth-based antigen that increases IgE levels in order to treat allergies.

It is the Examiner's position that the claims are drawn to a composition. The prior art anticipates the claimed invention because the intended use of the composition carries no patentable weight. The '158 patent teaches the migration inhibitory factor protein (MIF) of the Dirofilaria immitis and Onchocerca vulvulus parasitic helminths (In particular, column, 3, lines 5-37) and use thereof in a vaccine. The reference also teaches recombinant cells that include the parasitic MIF nucleic acid molecules (In particular, column 3, lines 38-43). The compositions comprising the MIF protein are administered in an immunogenic amount (In particular, column 23, lines 31-50) with a variety of adjuvants and carriers (In particular, column 22, lines 51 to

column 23, line 3) in a variety of formulations (injectable fluids) (In particular, column 22, lines 31-50).

A composition is a composition, regardless of its intended use. Therefore, the reference teachings anticipate the claimed invention.

Claims 1-2, 8 and 11 are included in this rejection because the term "derived" in claim 1 opens the claim up to include any protein that is "derived" from Capillaria hepatica or Dicrocoelium dendtritium, which include any number of substitutions, deletions or additions. Therefore, any protein of Dirofilaria immitis and Onchocerca vulvulus having any degree of homology to any protein of Capillaria hepatica or Dicrocoelium dendtritium anticipates the claimed invention. Further, claims 1-2, 8 and 11-12 are included in this rejection because the claimed functional limitation (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens) would be an inherent property of the referenced pharmaceutical formulation. When a claim recites using an old composition or structure (e.g. helminth based antigen pharmaceutical formulation) and the use is directed to a result or property of that composition or structure (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52

USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The prior art teachings anticipate the claimed invention.

13. Claims 1-2, 8 stand 11-12 stand rejected under 102(b) as being anticipated by U.S. Patent 5,996,758 (IDS filed on 09/19/2006) for the same reasons as set forth in the Office Action mailed on 03/19/2007.

Applicant's arguments filed on 07/23/2007 have been fully considered, but are not found persuasive.

Applicant argues that there is no teaching, suggestion or motivation in the cited art to use a helminth-based antigen that increases IgE levels in order to treat allergies.

It is the Examiner's position that the claims are drawn to a composition. The prior art anticipates the claimed invention because the intended use of the composition carries no patentable weight. The '758 patent teaches cysteine protease, a secretory protein accumulated in the tissue of the Paragonimus westermani parasitic helminths. The protein (helminth-based antigen comprising a protein derived from Capillaria hepatica or Dicrocoelium dendtritium) is extracted (extract) and purified and put in a pharmaceutical composition with Freund's adjuvant and injected into rabbits (In particular, column 3, lines 32 to 48). Pharmaceutical compositions

of helminthic cysteine protease can be in various forms including injectable solutions (In particular, column 10, lines 14 -20). The protein may also be produced recombinantly in cultured animal cells transformed with the nucleic acid (column 10, lines 25-31).

A composition is a composition, regardless of its intended use. Therefore, the reference teachings anticipate the claimed invention.

Claims 1-2, 8 and 11 are included in this rejection because the term "derived" in claim 1 opens the claim up to include any protein that is "derived" from Capillaria hepatica or Dicrocoelium dendtritium, which include any number of substitutions, deletions or additions. Therefore, any protein of Paragonimus westermani having any degree of homology to any protein of Capillaria hepatica or Dicrocoelium dendtritium anticipates the claimed invention. Further, claims 1-2 and 11-12 are included in this rejection because because the claimed functional limitation (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens) would be inherent properties of the referenced pharmaceutical formulation. When a claim recites using an old composition or structure (e.g. helminth based antigen pharmaceutical formulation) and the use is directed to a result or property of that composition or structure (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex

parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The prior art teachings anticipate the claimed invention.

14. Claims 1-2 and 11-12 stand rejected under 102(b) as being anticipated by Gonzalez-Lanza et al. (PTO-892 mailed on 03/19/2007, Page 2, Reference U) for the same reasons as set forth in the Office Action mailed on 03/19/2007.

Applicant's arguments filed on 07/23/2007 have been fully considered, but are not found persuasive.

Applicant argues that there is no teaching, suggestion or motivation in the cited art to use a helminth-based antigen that increases IgE levels in order to treat allergies.

It is the Examiner's position that the claims are drawn to a composition. The prior art anticipates the claimed invention because the intended use of the composition carries no patentable weight. Gonzalez-Lanza et al. teaches the whole-worm extract (helminth-based antigen comprising a protein derived from Capillaria hepatica or Dicrocoelium dendtritium) of adult D. dendriticum (In particular, page 473, 'Preparation of Antigens' section). The reference also teaches the preparation of ES antigen (helminth-based antigen comprising a protein derived

from Capillaria hepatica or Dicrocoelium dendtritium) from D. dendriticum. Both whole-worm extract and ES antigen preparations were suspended in $NaHCO_3/NaCO_3$ (carrier/diluent).

A composition is a composition, regardless of its intended use. Therefore, the reference teachings anticipate the claimed invention.

Claims 1-2 and 11-12 are included in this rejection because because the claimed functional limitation (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens) would be inherent properties of the referenced pharmaceutical formulation. When a claim recites using an old composition or structure (e.g. helminth based antigen pharmaceutical formulation) and the use is directed to a result or property of that composition or structure (increases said mammal's blood serum levels of Immunoglobulin E levels (IgE) to greater than about 3,000 IU/ml thereby ameliorating the allergic reaction of said mammal to a plurality of antigens), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The prior art teachings anticipate the claimed invention.

15. No claim is allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

August 2, 2007

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

Maher M. Haddad

MAHER M. HADDAD
PRIMARY EXAMINER